NOV 13 2008

510(K) SUMMARY
(as required by 807.92(c))

Regulatory Correspondent: AJW Technology Consultants Inc.
962 Allegro Lane
Apollo Beach, FL 33572

Phone: (813) 645-2855

Submitter of 510(k): GrantAdler Corporation
1733 Park Street Suite 104
Naperville, IL 60563

Phone: 800-605-4815

Contact Person: Michael Loiterman

Date of Summary: July 3, 2008

Trade/Proprietary Name: Rhapsody MRI

Classification Name: Port & catheter, implanted, subcutaneous, intravascular

Product Code: LJT

Device Description:
grantAdler Ports and Catheters are supplied as sterile devices, and are intended for single patient use only. The ports are available as a single model and are manufactured of the highest quality titanium. They also incorporate a durable high compression self-sealing silicone septum. Catheter materials include flexible, non-compressible, and reinforced silicone. Suture sites are incorporated into the port base to facilitate anchorage to the underlying fascia. The grantAdler port line is indicated for any patient requiring reliable repeated access of the vascular system for delivery of medications, nutritional supplementation, fluids, blood, blood products, or the sampling of blood.

Predicate Device:
K043178 – GrantAdler - Rhapsody

Substantial Equivalence:
The Rhapsody MRI meets all established acceptance criteria for performance testing and design verification testing. The components of the Rhapsody MRI are substantially equivalent to the predicate devices as presented in this 510(k). The product is identical to the GrantAdler Rhapsody Access Port with different labeling and testing having been performed to demonstrate its substantial equivalence as a MRI Compatible Device.

Intended Use:
The grantAdler Rhapsody Access Port and Catheter is indicated for any patient requiring reliable repeated access of the vascular system for delivery of medications, nutritional supplementation, fluids, blood, blood products or the sampling of blood. The Rhapsody Port and Catheter are safe to use in an MRI environment.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 13 2008

GrantAdler Corporation
C/O Arthur J. Ward, Ph.D.
AJW Technology Consultants Incorporated
962 Allegro Lane
Apollo Beach, Florida 33572

Re: K082126
Trade/Device Name: Rhapsody MRI
Regulation Number: 21 CFR 880.5965
Regulation Name: Subcutaneous, Implanted, Intravascular Infusion Port and Catheter
Regulatory Class: II
Product Code: LJT
Dated: July 3, 2008
Received: August 19, 2008

Dear Dr. Ward:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu S. Lin, Ph. D
Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K082126

Indications for Use

510(k) Number (if known): _____

Device Name: Rhapsody MRI

Indications for Use:

The grantAdler Rhapsody Access Port and Catheter is indicated for any patient requiring reliable repeated access of the vascular system for delivery of medications, nutritional supplementation, fluids, blood, blood products or the sampling of blood.

Prescription Use ___X_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K082126